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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,589

07/28/2003

Deborah Cook

030421.002

4629

34142 7590 12/04/2008
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EXAMINER

SQUIRES, ELIZA A

ART UNIT

PAPER NUMBER

4156

MAIL DATE

DELIVERY MODE

12/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/628,589	Applicant(s) COOK, DEBORAH	
	Examiner Eliza Squires	Art Unit 4156	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/28/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This communication is in response to the application filed on 7/28/2003. Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-4, 6-7, 10-13, and 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,379,885 to *Zakim* in view of U.S. Patent 5,845,264 to Nellhaus, hereinafter referred to as *Nellhaus* ('264).

4. **As to claim 1**, *Zakim* discloses an interactive multi-user medication and medical history management method, comprising the steps of:

creating at least one user profile by entering a plurality of user data (*Zakim* column 11 lines 54-67 and column 12 lines 1-23);

generating at least one patient record including a patient medical history and a patient medication profile having at least one prescribed medication, at least one medication formulation requirement, , wherein the patient medication profile is created in part by accessing a predetermined master medication library, resident in at least one memory medium, having a plurality of medication data for a plurality of medications (*Zakim* column 20 lines 4-31, column 11 lines 54-67, and column 12 lines 1-23);

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storing the at least one user profile and the at least one patient record and the master medication library on the at least one memory medium (*Zakim* column 13 lines 42-55);

applying a user specified report generating filter to the at least one patient record to create at least one administration and history report (*Zakim* column 21 lines 22-57); and

displaying the at least one administration and history report (*Zakim* column 21 lines 22-57).

However, *Zakim* does not explicitly teach a medication administration requirement and a pictorial representation of the medications. *Nellhaus* ('264) discloses at least one medication administration requirement and including at least one pictorial representation of each of the plurality of medications (*Nellhaus* ('264) column 3 lines 53-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* with *Nellhaus* ('264) since it would allow the patient and the physician to make more informed decisions by having more information more readily available.

5. **As to claim 2**, see the discussion of claim 1, additionally, *Zakim* further discloses the method wherein the at least one memory medium wherein the predetermined master medication library resides is located in a first computer system in communication with a separate and distinct second computer system wherein the user profile creation step is initiated, wherein the report generating filter applying step is initiated, and wherein the displaying step occurs (*Zakim* column 13 lines 42-55).

6. **As to claim 3**, see the discussion of claim 2, additionally, *Zakim* discloses the method wherein the first computer system and the second computer system are in communication over the Internet (*Zakim* column 13 lines 33-54).

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7. **As to claim 4**, see the discussion of claim 1, additionally, *Zakim* discloses the method wherein the user data includes at least one access permission level assignment for each of the at least one user profiles thereby associating any of the at least one patient records with any of the at least one access permission level assignments thereby permitting a user, associated with the user data, to access only the at least one patient records associated with the at least one access permission level assignment (*Zakim* column 36 lines 49-62).
8. **As to claim 6**, see the discussion of claim 1, additionally, *Nellhaus ('264)* discloses the method wherein the at least one administration and history report includes at least one pictorial representation of each of the at least one prescribed medication (*Nellhaus ('264)* column 3 lines 53-61).
9. **As to claim 7**, see the discussion of claim 1, additionally, *Nellhaus ('264)* discloses the method wherein the at least one administration and history report includes at least one administration indicia (*Nellhaus ('264)* column 3 lines 53-61).
10. **As to claim 10**, see the discussion of claim 1, additionally, *Nellhaus ('264)* discloses the method wherein the at least one administration and history report is adapted for ease of use and handling, and is sized to fit in a wallet (*Nellhaus ('264)* claim 4).
11. **As to claim 11**, see the discussion of claim 1, additionally, *Nellhaus ('264)* discloses the method wherein the at least one administration and history report is adapted to be printed on a medication bottle sticker (*Nellhaus ('264)* claim 8).
12. **As to claim 12**, see the discussion of claim 1, additionally, *Nellhaus ('264)* discloses the method wherein the plurality of medication data for the plurality of medications includes a drug

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interaction profile for each of the plurality of medications (*Nellhaus* ('264) column 5 lines 62-65 and column 6 lines 1-10).

13. **As to claim 13**, see the discussion of claims 1 and 12, additionally, *Nellhaus* ('264) discloses the method wherein the user specified report generating filter compares the drug interaction profile of each of the at least one prescribed medication in the patient medication profile and displays at least one interaction warning indicia for any of the at least one prescribed medication known to interact with any other of the at least one prescribed medication in the patient medication profile (*Nellhaus* ('264) column 5 lines 62-65 and column 6 lines 1-10).

14. **As to claim 17**, see the discussion of claim 1, additionally, *Zakim* discloses the method wherein the patient medical history includes an allergy alert profile containing known allergies for each of the at least one patient records (*Zakim* column 25 lines 1-5).

15. **As to claim 18**, see the discussion of claims 1 and 17, additionally, *Zakim* discloses the method wherein the user specified report generating filter compares the allergy alert profile with each of the at least one prescribed medication and displaying allergy warning indicia for any of the at least one prescribed medication appearing in the allergy alert profile (*Zakim* column 28 lines 50-65 and column 25 lines 1-5).

16. **As to claim 19**, *Zakim* discloses An interactive multi-user medication and medical history management method, comprising the steps of:

creating at least one user profile by entering a plurality of user data user data including at least one access permission level assignment for each of the at least one user profiles thereby associating any of the at least one patient records with any of the at least one access permission level assignments thereby permitting a user, associated with the user data, to access only the at

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least one patient records associated with the at least one access permission level assignment (*Zakim* column 36 lines 41-62);

generating at least one patient record including a patient medical history wherein the patient medical history includes an allergy alert profile containing known allergies for each of the at least one patient records and a patient medication profile having at least one prescribed medication, at least one medication formulation requirement, wherein the patient medication profile is created in part by accessing a predetermined master medication library, resident in at least one memory medium, having a plurality of medication data for a plurality of medications, storing the at least one user profile and the at least one patient record and the master medication library on the at least one memory medium (*Zakim* column 25 lines 1-5, column 20 lines 4-31, column 11 lines 54-67, and column 12 lines 1-23);

applying a user specified report generating filter to the at least one patient record to create at least one administration and history report (*Zakim* column 13 lines 42-55); and

However, *Zakim* does not explicitly teach a medication administration requirement and a pictorial representation of the medications. *Nellhaus* ('264) discloses:

at least one medication administration requirement (*Nellhaus* ('264) column 3 lines 53-61);

a drug interaction profile for each of the plurality of medications and at least one pictorial representation of each of the plurality of medications (*Nellhaus* ('264) column 5 lines 62-65, column 6 lines 1-10 and column 3 lines 53-61);

displaying the at least one administration and history report wherein the at least one administration and history report includes at least one pictorial representation of each of the at

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least one prescribed medication and at least one administration indicia (*Nellhaus* ('264) column 3 lines 53-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* with *Nellhaus* ('264) since it would allow the patient and the physician to make more informed decisions by having more information more readily available.

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17. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in view of *Nellhaus* ('264) in further view of U.S. Patent 4,878,175 to *Norden-Paul*.

18. **As to claim 5**, *Zakim* and *Nellhaus* ('264) in combination disclose the system substantially as claimed in claim 1, however, the references do not explicitly teach a read-only limiter. *Norden-Paul* discloses the method wherein the at least one permission level assignment includes at least one read-only limiter, associated with at least a portion of the at least one patient record, to enable a user to view the at least one patient records associated with the at least one access permission level assignment, but guard the permitted patient records from modification by the user (*Norden-Paul* column 14 lines 29-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* and *Nellhaus* ('264) with *Norden-Paul* since the combination would improve record security by preventing unauthorized users from modifying records.

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19. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in view of *Nellhaus* ('264) in further view of U.S. Patent 5,031,937 to Nellhaus, hereinafter referred to as *Nellhaus* ('937).

20. **As to claim 8**, *Nellhaus* ('264) and *Zakim* in combination disclose the system substantially as claimed in claim 1 and 7, however, the references do not explicitly teach a time of day of administration. *Nellhaus* ('937) discloses the method wherein the at least one administration indicia is representative of a time of day that the at least one prescribed medication is preferably administered (*Nellhaus* ('937) figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of *Nellhaus* ('264) and *Zakim* with *Nellhaus* ('937) since the combination would improve the ability of a patient to understand how a medication is to be taken in order to improve their health.

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21. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in view of *Nellhaus* ('264) in further view of "Best Practice Guidance on Labeling and Packaging of Medicines" by *MHRA*.

22. **As to claim 9**, *Nellhaus* ('264) and *Zakim* in combination disclose the system substantially as claimed in claim 1 and 7, however, the references do not explicitly teach a method of administration. *MHRA* discloses the method wherein the at least one administration indicia is representative of a method of administration (*MHRA* section 4.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of *Nellhaus* ('264) and *Zakim* with *MHRA* since the combination would improve the ability of a patient to understand how a medication is to be taken in order to improve their health.

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23. **Claims 14-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in view of *Nellhaus* ('264) in further view of U.S. Patent application 2002/0019749 to *Becker et al.*

24. **As to claim 14**, *Zakim* and *Nellhaus* ('264) in combination disclose the system substantially as claimed in claim 1, however, the references do not explicitly teach a medication refill reminder. In the same field of endeavor, *Becker* discloses the method including the step of generating at least one medication refill reminder a predetermined number of days prior to the exhaustion of the at least one prescribed medication by utilizing the at least one medication formulation requirement and the at least one medication administration requirement (*Becker* paragraphs [0111] and [0115]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* and *Nellhaus* ('264) with *Becker* since the combination would improve the prevention of delay in a patient receiving their medications, thereby improving a patients health.

25. **As to claim 15**, see the discussion of claims 1 and 14, additionally, *Becker* discloses the method wherein the at least one medication refill reminder is automatically emailed from the first computer system to the second computer system (*Becker* paragraph [0115]).

26. **As to claim 16**, see the discussion of claims 1 and 14, additionally, *Becker* discloses the method wherein the at least one medication refill reminder is automatically emailed from the first computer system to a site outside of the first and the second computer system (*Becker* paragraph [0115]).

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27. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in further view of *Nellhaus* ('264) in further view of *Norden-Paul* in further view of *Nellhaus* ('937).

28. **As to claim 20**, *Zakim* discloses an interactive multi-user medication and medical history management method, comprising the steps of:

generating at least one patient record including a patient medical history wherein the patient medical history includes an allergy alert profile containing known allergies for each of the at least one patient records and a patient medication profile having at least one prescribed medication, at least one medication formulation requirement, wherein the patient medication profile is created in part by accessing a predetermined master medication library, resident in a first computer system in communication with a second separate and distinct computer system, having a plurality of medication data for a plurality of medications, storing the at least one user profile and the at least one patient record and the master medication library on the at least one memory medium (*Zakim* column 25 lines 1-5, column 20 lines 4-31, column 11 lines 54-67, column 12 lines 1-23, and column 13 lines 42-55);

storing the at least one user profile and the at least one patient record on the second computer system in communication with the first computer system containing the master medication library (*Zakim* column 13 lines 42-55);

applying a user specified report generating filter in the second computer system to the at least one patient record to compare the drug interaction profile of each of the at least one prescribed medication in the patient medication profile and display at least one interaction warning indicia for any of the at least one prescribed medication known to interact with any other of the at least one prescribed medication in the patient medication profile and to compare

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the allergy alert profile with each of the at least one prescribed medication and displaying allergy warning indicia for any of the at least one prescribed medication appearing in the allergy alert profile and to create at least one administration and history report (column 28 lines 34-65 and column 21 lines 22-57); and

However, *Zakim* does not explicitly teach a medication administration requirement and a pictorial representation of the medications. *Nellhaus* ('264) discloses:

at least one medication administration requirement (*Nellhaus* ('264) column 3 lines 53-61);

a drug interaction profile for each of the plurality of medications and at least one pictorial representation of each of the plurality of medications (*Nellhaus* ('264) column 5 lines 62-65, column 6 lines 1-10 and column 3 lines 53-61);

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* with *Nellhaus* ('264) since it would allow the patient and the physician to make more informed decisions by having more information more readily available.

However, *Zakim* and *Nellhaus* ('264) in combination do not explicitly teach a read-only limiter. In the same field of endeavor, *Norden-Paul* discloses:

creating at least one user profile by entering a plurality of user data user data including at least one access permission level assignment wherein the at least one permission level assignment includes at least one read-only limiter, associated with at least a portion of the at least one patient record, to enable the user to view the at least one patient records associated with the at least one access permission level assignment, but guard the permitted patient records from modification by the user, for each of the at least one user profiles thereby associating any of the

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at least one patient records with any of the at least one access permission level assignments thereby permitting a user, associated with the user data, to access only the at least one patient records associated with the at least one access permission level assignment (*Norden-Paul* column 14 lines 29-38);

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim* and *Nellhaus* ('264) with *Norden-Paul* since the combination would improve record security by preventing unauthorized users from modifying records.

However *Zakim*, *Nellhaus* ('264) and *Norden-Paul* do not explicitly teach a time of day that the prescription is administered. In the same field of endeavor *Nellhaus* ('937) discloses:

displaying the at least one administration and history report on the second computer system wherein the at least one administration and history report includes at least one pictorial representation of each of the at least one prescribed medication and at least one administration indicia representative of a time of day that the at least one prescribed medication is preferably administered (*Nellhaus* ('937) figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of *Zakim*, *Nellhaus* ('264) and *Norden-Paul* with *Nellhaus* ('937) since the combination would improve the ability of a patient to understand how a medication is to be taken in order to improve their health.

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29. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zakim* in further view of *Nellhaus* ('264) in further view of *Norden-Paul* in further view of *Nellhaus* ('937) in view of U.S. Patent 6,386,367 to *Bayliss*.

30. **As to claim 21**, *Zakim*, *Nellhaus* ('264), *Norden-Paul*, and *Nellhaus* ('937) in combination disclose the system substantially as disclosed in claim 20, however the references do not explicitly teach that the pictorial representation is in accurate scale and color. *Bayliss* discloses the method wherein the pictorial representation of each of the at least one prescribed medications is in accurate scale and coloration to the at least one prescribed medication (*Bayliss* column 5 lines 40-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Zakim*, *Nellhaus* ('264), *Norden-Paul*, and *Nellhaus* ('937) with *Bayliss* since the combination would improve the ability of patient or practitioner to identify pills, preventing their misuse.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Kyle can be reached on 571-272-6746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./

Examiner, Art Unit 4156

11/24/08

/Charles R. Kyle/

Supervisory Patent Examiner, Art Unit 4156